

SEP 29 2004

510(k) Summary
(as required by 21 CFR 807.92)

A. Submitter Information

Submitter's Name: Medtronic Perfusion Systems
Address: 7611 Northland Drive N
Minneapolis, Minnesota
55428-1088 U.S.A.
Telephone Number: 763.391.9000
Contact Person: Bruce Backlund
Date Submission Prepared: July 02, 2004

B. Device Information

Common or usual Name: Syringe
Classification Name: Piston Syringe
Predicate Device: 1) Magellan Ratio Dispenser Kit,
Medtronic, Inc
K020147 – 04/03/2002
2) Harvest Technologies Dual Liquid Applicator,
Harvest Technologies
K020252 – 04/05/2002
Device Description: The Magellan Ratio Dispenser Kit consists of the following components:

- 12 cc legally marketed disposable piston syringe
- 1 cc legally marketed disposable piston syringe
- Dispenser Handle
- Plunger clip
- Dual channel tip (spray or cannula)
- Two medicine cups

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Indications for Use:

The Magellan™ Ratio Dispenser Kit is intended for the application of fluids, as deemed necessary by the surgeon's determination of the clinical use requirements, to facilitate the preparation of soft tissue prior to repair.

C. Comparison of Required Technological Characteristics

The technological characteristics of the Magellan™ Ratio Dispenser Kit are substantially equivalent to the predicate devices including product design, materials, packaging, and sterilization.

D. Performance Data

Performance data that supports the safety and effectiveness of the use of Magellan Ratio Dispenser Kit is included in the submission. This data is unchanged from the predicate, which is our currently marketed Magellan Ratio Dispenser kit (K020147).

E. Conclusion

Medtronic Perfusion Systems considers the Magellan Ratio Dispenser Kit to be substantially equivalent to the noted predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 29 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Bruce Backlund
Senior Regulatory Affairs Specialist
Medtronic Perfusion Systems
7611 Northland Drive N
Minneapolis, Minnesota 55428

Re: K041830
Trade/Device Name: Magellan Ratio Dispenser Kit
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: II
Product Code: FMF
Dated: July 2, 2004
Received: July 7, 2004

Dear Mr. Backlund:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

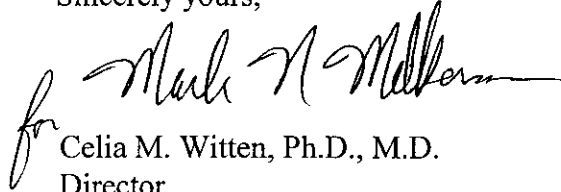
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041830

Device Name: Magellan Ratio Dispenser Kit


Indications For Use:

The Magellan Ratio Dispenser Kit is intended for the application of fluids, as deemed necessary by the surgeon's determination of the clinical use requirements, to facilitate the preparation of soft tissue prior to repair.

Prescription Use X AND/OR
(Part 21 CFR 801 Subpart
D)

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)


Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

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